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ART UNIT	PAPER NUMBER
1639	

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32

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/163,199	Fukushima et al
Examiner	**Art Unit**
Maurie G. Baker, Ph.D.	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *THREE* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 16, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 7, and 8* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 7, and 8* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Please note: The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to Art Unit **1639**.

1. Applicant's Response filed April 16, 2003 (Paper No. 31) is acknowledged. Claim 1 was amended. Currently, claims 1, 7 and 8 are pending and under examination.

Status of Rejections

2. The previous rejections under 35 U.S.C. 112, first paragraph and second paragraph have been withdrawn in view of applicant's claim amendments and arguments. The previous art rejections are maintained but have been slightly rewritten as necessitated by applicant's amendments. New rejections necessitated by applicant's amendment are also set forth in this action.

New Rejections – Necessitated by Amendment
Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed fails to support the invention as now claimed. Amended claim now recites that "the transducing element comprises a thin film transistor that transduces a difference between a predetermined voltage and a voltage generated by a constant current flowing through a solution applied between the microelectrodes into an electric signal corresponding to the difference". Applicant points to pages 12 and 13 of the instant specification for support; however, the cited portions of the specification only provides general support for measuring changes in electric impedance of electrodes coated with a film after adsorption of gaseous analytes. The examiner deems that this is **not** sufficient support for the specific limitation wherein "the transducing element comprises a thin film transistor that transduces a difference between a predetermined voltage and a voltage generated by a constant current flowing through a solution applied between the microelectrodes into an electric signal corresponding to the difference". There does not appear to be support for the concept of the transducing element transducing "a *difference* between a *predetermined voltage* and a *voltage generated by a constant current flowing through a solution applied between the microelectrodes* into an *electric signal corresponding to the difference*"(emphasis added). Note that a broad generic disclosure is not sufficient support for a specific entity within the class.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 now recites that "the transducing element comprises a thin film transistor that transduces a difference between a predetermined voltage and a voltage generated by a constant current flowing through a solution applied between the microelectrodes into an electric signal corresponding to the difference". This is highly confusing, unclear and renders the claims indefinite. First, it is unclear what the "predetermined voltage" is as well as the "voltage generated by a constant current flowing through a solution applied between the microelectrodes" and also the " electric signal corresponding to the difference".

The term "predetermined" is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. How is this voltage predetermined, i.e. under what conditions?

Additionally, amended claim 1 recites in the beginning of the claim that the sensor device has "a transducing element that transduces change in electric impedance in connection with absorbing aromatic molecules inside the organic film into electric signals". Is this the same transducing element as described in the newly added limitation? It is completely unclear. As pointed out by applicant in the response filed April 16, 2003, the recitation in the beginning of the claim appears to correspond to the

adsorption of molecules from the *gas phase* into the film (instant specification, pages 12 and 13). Now the claim also contains a limitation concerning a "voltage generated by a constant current *flowing through a solution applied between the microelectrodes*" (emphasis added). This is very confusing. Moreover, where did this solution come from? It has no antecedent basis in the claim.

Lastly, and most importantly, the newly added limitation that "the transducing element comprises a thin film transistor *that transduces a difference between a predetermined voltage and a voltage generated by a constant current flowing through a solution applied between the microelectrodes into an electric signal corresponding to the difference*" does not appear to further limit the claimed "method of manufacturing a sensor device" with respect to the emphasized portion. This is because the added limitation appears to only be directed to the intended use of the claimed sensor device. Note that an intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

Maintained Rejections
Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Please note that the art rejections below are maintained but have been slightly rewritten as necessitated by applicant's amendments. Applicant's arguments are addressed following the rejections (paragraphs 14-19).

10. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musho et al (US 5,250,439; of record) in view of Hayes et al (US 4,877,745).

Please note: For the purposes of this rejection, *any* transducing element is deemed to be capable of transducing "change in electric impedance in connection with absorbing

aromatic molecules inside the organic film into electric signals" and also transducing "a difference between a predetermined voltage and a voltage generated by a constant current flowing through a solution applied between the microelectrodes into an electric signal corresponding to the difference". The instant claims are highly indefinite (are they the same transducing element?; what is the "predetermined voltage", the "solution" and the "difference"?) and do not appear to be supported by the instant specification. See rejections under 35 U.S.C. 112 set forth above. If the prior art structure is capable of performing the intended use, then it meets the claim. The Office does not have the facilities to make a comparison and the burden is on the applicants to establish any difference between the transducing elements of the art and the instant claims. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Musho et al teach a conductive sensor and use in diagnostic assay where the sensor is miniaturized and uses a conducting polymer (see Abstract). The sensors "utilize the unique electrical properties of conducting polymers to determine the presence and concentration of a predetermined analyte" (see column 12, lines 9-12) and are based on "the oxidative doping of a conducting polymer" such as a polythiophene (see column 16, line 58-63, for example). The conductive sensor "allows an accurate and sensitive electrical transduction of an analyte-oxidase interaction" (see column 12, lines 48-50) reading on the transducing element of the instant claims. Specifically, Figure 2 of the reference shows microelectrodes having a "gap" filled with conducting polymer. This polymer is applied as a "thin, uniform layer or film" (see column 21, lines 55-61, for

example). The conductive polymers used by Musho are especially chosen for their processibility in solution and can be applied by ink-jet printing (see column 22, lines 49-65). See especially column 31, lines 53-65 which discusses the manufacture of the sensors using conductive polymers in solution. As an organic thin film is made on the microelectrodes of the reference, this is deemed to read on the limitation in step (b) of "ejecting the solution via the ink jet nozzle". Using plastic as a base is also disclosed, see column 41, lines 1-2, reading on claim 7.

With respect to the limitation that the solution has a viscosity "of about 3 centipoise or less", it is noted that "[p]roducts of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Since the reference discloses a solution comprising "an electro-conductive polymer and a solvent" as set forth in the claims, this solution is deemed to have the properties applicant discloses.

Musho et al lacks the specific teachings with respect to the ink jet nozzle and operation of the ink jet (i.e. step (a)).

However, these teachings simply represent the standard operation of an ink jet printing device that were well-established in the art at the time of filing. For example, Hayes et al teach "a system for printing and dispensing chemical reagents" using a "jetting tube" which is "mounted within a cylindrical piezo-electric transducer" (see Abstract and Figures 1-4 & 6-8 and accompanying text). An electrical signal is applied

to the transducer which causes an expansion (and drawing in of fluid) and when the signal is stopped, a de-expansion, thus ejecting the fluid as a droplet (also see Abstract). This reads directly on the limitations set forth for the ink jet nozzle (i.e. deformation of piezo-electric element) and those in step (a) of instant claim 1. Moreover, Hayes et al teaches that an advantage of using ink jet printing of reagents is that "precise minute quantities of reagent fluid may be dispensed or printed in a reproducible manner" and that "the method and apparatus may be used to emit droplets of fluids having a wide range of reagent fluid viscosities and surface tensions" (column 3, lines 44-51).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to use the standard methodology for ink jet printing in the creation of the sensors of Musho et al. One of ordinary skill would be motivated to do so since Musho et al specifically recites that the conductive polymers used in their sensors can be applied by ink-jet printing and the technology of ink jet printing of chemical reagents was well established in the art as taught by Hayes et al. One would also be motivated to use ink jet printing for manufacturing sensors with thin films thereon due to the known advantages of such a technique. These advantages are taught in Hayes et al, see above.

11. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (US 5,571,401; of record) in view of Hayes et al (US 4,877,745).

Please note: For the purposes of this rejection, *any* transducing element is deemed to be capable of transducing "change in electric impedance in connection with absorbing aromatic molecules inside the organic film into electric signals" and also transducing "a

difference between a predetermined voltage and a voltage generated by a constant current flowing through a solution applied between the microelectrodes into an electric signal corresponding to the difference". The instant claims are highly indefinite (are they the same transducing element?; what is the "predetermined voltage", the "solution" and the "difference"?) and do not appear to be supported by the instant specification. See rejections under 35 U.S.C. 112 set forth above. If the prior art structure is capable of performing the intended use, then it meets the claim. The Office does not have the facilities to make a comparison and the burden is on the applicants to establish any difference between the transducing elements of the art and the instant claims. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Lewis et al teach chemical sensors for detecting analytes in fluids (see Abstract and Figures 1A-B). These sensors contain nonconductive and conductive materials; the conductors can be organic conductors such as polymers (see column 4, lines 20-27). The materials can both be soluble in a common solvent, see column 5, especially lines 14-54 regarding the conductive polymer poly(pyrrole). The resistance of the film changes upon sorption of an analyte, thus transducing the interaction into an electrical signal (reading on the transducing element of the instant claims), see column 6, lines 9-28, for example. Fabrication of sensors using poly(pyrrole) is specifically disclosed, see column 8, lines 34-54. Lewis teaches that sensor arrays can be scaled up to IC design technologies and can be produced by ink-jet technology (column 6, lines 47-67).

With respect to the limitation that the solution has a viscosity "of about 3 centipoise or less", it is noted that "[p]roducts of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Since the reference discloses a solution comprising "an electro-conductive polymer and a solvent" as set forth in the claims, this solution is deemed to have the properties applicant discloses.

Lewis et al lacks the specific teachings with respect to the ink jet nozzle and operation of the ink jet (i.e. step (a)).

However, these teachings simply represent the standard operation of an ink jet printing device that were well-established in the art at the time of filing. For example, Hayes et al teach "a system for printing and dispensing chemical reagents" using a "jetting tube" which is "mounted within a cylindrical piezo-electric transducer" (see Abstract and Figures 1-4 & 6-8 and accompanying text). An electrical signal is applied to the transducer which causes an expansion (and drawing in of fluid) and when the signal is stopped, a de-expansion, thus ejecting the fluid as a droplet (also see Abstract). This reads directly on the limitations set forth for the ink jet nozzle (i.e. deformation of piezo-electric element) and those in step (a) of instant claim 1. Moreover, Hayes et al teaches that an advantage of using ink jet printing of reagents is that "precise minute quantities of reagent fluid may be dispensed or printed in a reproducible manner" and that

"the method and apparatus may be used to emit droplets of fluids having a wide range of reagent fluid viscosities and surface tensions" (column 3, lines 44-51).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to use the standard methodology for ink jet printing in the creation of the sensors of Lewis et al. One of ordinary skill would be motivated to do so since Lewis et al specifically recites their sensors can be can be produced by ink-jet printing and the technology of ink jet printing of chemical reagents was well established in the art as taught by Hayes et al. One would also be motivated to use ink jet printing for manufacturing sensors with thin films thereon due to the known advantages of such a technique. These advantages are taught in Hayes et al, see above.

12. Claims 1, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musho et al (US 5,250,439; of record) in view of Hayes et al (US 4,877,745) and further in view of Smith et al (US 4,874,499).

The teachings of Musho et al and Hayes et al are set forth in the rejection above (paragraph 10).

The references lack the teaching of specifically using poly-silicon thin film transistors in the sensor (i.e., claim 8). However, such thin film transistors were well established in the art at the time of filing. For example, Smith et al teach the formation of electrochemical microsensors that can be formed from a wide variety of materials (for both the substrate and overlying structure) (see Abstract). Conventional integrated circuit processing techniques can be used and essentially "any means for sensing and

transmitting potential or current from the sensing site can be utilized" including FETs having polysilicon gates (see column 6, lines 1-25, for example). Moreover, a variety of substrates can be used for the microsensors, including organic resins (column 6, lines 33-38).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use art-standard poly-silicon thin film transistors in the sensors of Musho et al. One of ordinary skill would have been motivated to do so in order to be able to use art-standard circuitry and conventional integrated circuit processing techniques in the manufacture of such microsensors.

13. Claims 1, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (US 5,571,401; of record) in view of Hayes et al (US 4,877,745) and further in view of Smith et al (US 4,874,499).

The teachings of Lewis et al and Hayes et al are set forth in the rejection above (paragraph 11).

The references lack the teaching of specifically using poly-silicon thin film transistors in the sensor (i.e., claim 8). However, such thin film transistors were well established in the art at the time of filing. For example, Smith et al teach the formation of electrochemical microsensors that can be formed from a wide variety of materials (for both the substrate and overlying structure) (see Abstract). Conventional integrated circuit processing techniques can be used and essentially "any means for sensing and transmitting potential or current from the sensing site can be utilized" including FETs

having polysilicon gates (see column 6, lines 1-25, for example). Moreover, a variety of substrates can be used for the microsensors, including organic resins (column 6, lines 33-38).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use art-standard poly-silicon thin film transistors in the sensors of Lewis et al. One of ordinary skill would have been motivated to do so in order to be able to use art-standard circuitry and conventional integrated circuit processing techniques in the manufacture of such microsensors.

Response to Arguments

14. Applicant's arguments filed April 16, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

15. Applicant argues that the newly added limitation that "the transducing element comprises a thin film transistor that transduces a difference between a predetermined voltage and a voltage generated by a constant current flowing through a solution applied between the microelectrodes into an electric signal corresponding to the difference" differentiates the instant claims from the art. The examiner respectfully disagrees for the following reasons.

16. First, applicants argue that the specification supports the amendment. The examiner's position is that the added limitation is new matter, see paragraph 4 above. Moreover, the added

limitation is highly confusing for a variety of reasons; see rejection under 35 U.S.C. 112, second paragraph above (paragraph 6). This makes interpretation of the claims difficult.

17. Also, applicant's explanation of support (Response, page 5) refers to elements that are not claimed. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., resistance sensor, differential amplifier) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally the relationship between the elements of the claim is completely unclear, see paragraph 6 above.

18. Lastly, as stated above, the newly added limitation that "the transducing element comprises a thin film transistor *that transduces a difference between a predetermined voltage and a voltage generated by a constant current flowing through a solution applied between the microelectrodes into an electric signal corresponding to the difference*" does not appear to further limit the claimed "method of manufacturing a sensor device" with respect to the emphasized portion. The added limitation appears to only be directed to the intended use of the claimed sensor device. Note that an intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a

manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

19. For these reasons, the art rejections are maintained.

Status of Claims/ Conclusion

20. No claims are allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703)

308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
June 27, 2003

MAURIE GARCIA BAKER PH.D
PRIMARY EXAMINER